

STATUS OF THE CLAIMS

Claims 1-26 and 32-47 are pending in the application. Claims 1-26 and 32-47 are subject to restriction and/or election of species. Claims 45, 46 and 47 have been amended. Support for the amendment can be found in claim 1 as originally filed. No new matter has been added.

REMARKS/ARGUMENTS

Claims 1-26, 32-47 remain in this application. By way of the present amendment, claims 45-47 have been made dependent on claim 1.

Elections/Restrictions

The Examiner asserts that restriction is required under 35 USC 121 and 372. The Examiner asserts that the application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Group I, claim(s) 1-26, 32-44, drawn to a protein separation device.

Group II, claim(s) 45-47, drawn to methods of isolating and identifying at least one protein from a biological sample.

The Examiner asserts that the claims do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same corresponding technical features for the following reasons: the common technical feature linking Groups I and II, namely a protein separation device comprising a chaperone protein immobilized on a substrate, is allegedly known in the prior art as evidenced by Nam *et al.*, *Protein Expression and Purification*, vol. 24, pgs. 282-291. The Examiner asserts that Nam teaches separation and affinity purification of chaperones, including GroEL, on a support, making reference to the abstract of Nam.

The Examiner further asserts that the application contains claims directed to more than one species of the generic invention as follows:

Species A - claims 5, 6 and 9 (claim 4 being the generic claim to which species A relates);

Species B - claims 17, 18 and 19 (claim 16 being the generic claim to which species B relates).

Applicants respectfully provisionally elect Group I, claims 1-26, 32-34 drawn to a separation device, with traverse. Within Group I, Applicants provisionally elect with traverse species A, i.e. the protein separation device in which the Group I chaperone is GroEL. Claims 1-26, 32-47 read on the elected species GroEL.

Applicants respectfully submit that the claims, as amended, do not lack unity of invention. Claims 45-47, as originally presented, recite a chaperone protein immobilised on a substrate. This corresponds to the protein separation device according to claim 1 comprising a chaperone protein immobilised on a substrate. For clarification, claims 45-47 have been made dependent on claim 1. Thus, the method claims have been made dependent on the product claims. 37 CFR 1.475(b) provides, in pertinent part, that:

An international or national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations or categories:

...

(2) A product and a process of use of said product....

As claims 45-47 having been made dependent on claim 1, the claims are directed to a product and the process of use of the product and thus are considered to have unity of invention pursuant to 37 CFR 1.475(b). Applicants therefore respectfully request withdrawal of the requirement for restriction.

Irrespective of the above, Applicants respectfully submit that the claims do not lack unity of invention because the protein separation device comprising a chaperone protein immobilised on a substrate is a common inventive technical feature of the claims that distinguishes over the

Nam reference cited by the Examiner. Nam does not disclose a protein separation device comprising a chaperone protein immobilised on a substrate, as claimed. Indeed, at page 282, second column, Nam states:

An ideal situation would be to immobilize molecular chaperones to enhance a protein folding but this may not be possible because the cascade or concerted action exhibited by chaperones and the oligomeric compositions of GroES and GroEL. (emphasis added)

Nam explains that the objective of their research was to affinity-purify molecular chaperones from *E. coli* cell lysates using immobilized β -CN (see Nam at page 283, second column). In Nam, β -CN was immobilised on the column and used to capture the chaperone protein. The chaperone protein was then eluted from the column to purify the chaperone protein. As explained in Nam (page 284, first and second columns) cold water (4°C) or 1 mM Mg-ATP in water was applied to dissociate interactions between β -CN and chaperones so that the chaperone protein would be eluted from the column.

Thus, Nam teaches the opposite configuration to the presently claimed invention. In Nam, the chaperone proteins were not immobilised on the column, in contrast to the present claims which require immobilisation of the chaperone. Indeed, in Nam the chaperones could not have been immobilised on the column or it would not have been possible to elute them using cold water or ATP. Unlike the present invention, Nam was not using the chaperone proteins to separate other proteins but rather was using a column to isolate the chaperone proteins themselves.

In this regard, solely by way of illustration, the Examiner is directed to Example 2 in the present specification wherein biotinylated GroEL was conjugated onto NeutrAvidin beads which were then packed into a column. Denatured human serum was applied to the column and proteins bound to the immobilised GroEL were eluted from the column with buffer W supplemented with 3 mM ATP. This is of course completely different from Nam in which ATP was used to release the chaperones which were not immobilised on the column.

Thus, Nam *et al.* does not teach or suggest a protein separation device or method of using such a device as presently claimed, and therefore the claims possess unity of invention over Nam.

Reconsideration and withdrawal of the requirement for restriction and election of species are, therefore, respectfully requested.

CONCLUSION

In view of the foregoing, early favorable consideration of this application is earnestly solicited. Applicants hereby petition for a two-month extension of time, the statutory period having expired on January 14, 2010 and the present response being filed on or before March 14, 2010. The Commissioner is hereby authorized to charge or credit any such extension fees or overpayment to Deposit Account No. 50-1901 (Reference #490352-3004/US).

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Respectfully submitted,

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